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10/562,203

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Jean-Luc Clement

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09/03/2008

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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/562,203 | Applicant(s) CLEMENT ET AL. | |
| | Examiner JAN CHRISTOPHER MERENE | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/23/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is the initial Office action based on the 10/562,203 application filed on April 10, 2006, which is a 371 pf PCT/IB04/02458, filed on June 24, 2004, which claims priority to US Provisional No. 60/490,520 filed on July 29, 2003, which also claims Foreign Priority to FR0307777 filed on June 27, 2003.

Specification

2. The disclosure is objected to because of the following informalities: Page 1 lines 11 recites "dint" which is unclear. Page 1 lines 28 recites "[...] member known comprises" which is grammatically awkward. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, the phrases "for example" and "such as" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of

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the claimed invention. See MPEP § 2173.05(d). Claim 1 also recites “vertebrae by *dint* thereof” in line 5 of the claim, which is also unclear and indefinite. The manner in which the applicant has claimed “body” is also unclear. The examiner assumes the body refers to one of the anchoring members.

Claim 4 recites the limitation “crimped wall” and “connecting part.” There is insufficient antecedent basis for this limitation in the claim. For examining purposes, the examiner will treat the “crimped wall” and “connecting part” as the “wall” and “part” recited in claim 1. Claim 4 also recites “using said clamping means” also makes the claim indefinite since the claim is towards a device.

Regarding Claim 10, the applicant uses “comprises” and “consisting” in the same pre-ambles. This is also indefinite and as such the examiner will treat the claim as “comprising.”

5. The examiner notes that parenthetical limitations have no bearing on the claim and such parenthetical limitations in the claims are only used for reference, for example in the Figures of the claims. The uses of “these” and “this” in the claims are also grammatically awkward. Although the examiner has not pointed out each and every 112 issue in the claims, the examiner respectfully requests the help of the applicant in correcting any 112 issues regarding antecedent basis, indefiniteness, etc. The examiner will treat the claims with art as best understood in view of the 112 rejections. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

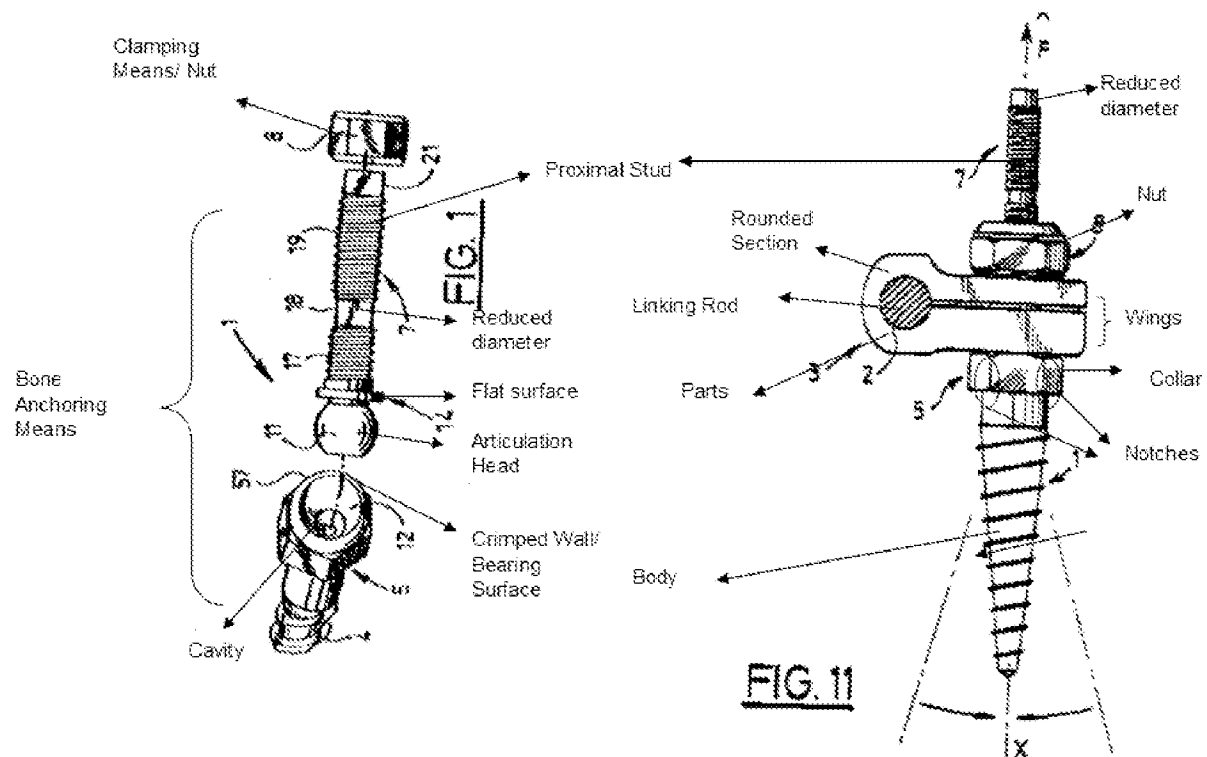
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-2, 4-11, 13, 15-16, 18,** are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al US 6,267,765.

Regarding **Claim 1**, Taylor et al discloses vertebral osteosynthesis equipment, including bony anchoring members, intended to be connected to these anchoring members and to be attached to the vertebrae, parts for connecting linking rod to the anchoring members, and clamping means for locking the linking rod in said connecting parts; at least one anchoring member is of the polyaxial type, comprising one proximal stud articulated with respect to a body intended for gripping a vertebra; equipment characterized in that the proximal stud of said polyaxial anchoring member exhibits an articulation head in the form of a spherical cap; and said body of the other anchoring member comprises a cavity intended for accommodating this articulation head and a wall surrounding the cavity, the wall being crimped around said articulation head and shaped in order to provide a proximal form, at least partially hemispherical (see Col 5 lines 1-7, where the wall is crimped around the articulation head and see Figs below and see Col 2 lines 65-67, Col 3 lines 1-12, where the articulation head is polyaxial).



Regarding **Claim 2**, Taylor et al discloses vertebral the body comprises a proximal gripping portion enabling to hold said body when tightening said clamping means, this proximal gripping portion being formed of a collar exhibiting several radial notches (see Fig above, where two notches are circled, where from the Figs, the collar exhibits multiple notches across the collar).

Regarding **Claims 4, 11**, Taylor et al discloses at least one connecting part exhibiting a rounded section intended for surrounding a linking rod and two parallel drilled wings, the wings intended for engaging onto said proximal stud and for being clamped, the clamping means is capable to bear against a surface contained in said

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polyaxial anchoring member; the distal wing of the connecting part exhibits a distal cavity (#10 see Fig 2) in the form of a spherical cap, which is of greater diameter than that the crimped wall, the connecting part being intended for resting against this crimped wall (#57 as seen in Fig 10) at of this cavity (see Figs above as well).

Regarding **Claim 5**, Taylor et al discloses the clamping means is a nut and the proximal branch of the connecting part comprises a proximal cavity (#10 as seen in Fig 2 and see also Fig 10) wherein a corresponding zone exhibited by this nut is intended for engaging.

Regarding **Claim 6**, Taylor et al discloses the cavity (#10 see Figs 2, 10) and said corresponding zone of the nut are conical in shape (see Figs above as well as Figs 2 and 10).

Regarding **Claims 7, 13, 15** Taylor et al discloses the stud exhibits a zone of reduced diameter, enabling to break its proximal portion after placing and clamping the nut (see Figs above and see Col 5 lines 31-42).

Regarding **Claims 8-9, 16, 18**, Taylor et al discloses the proximal stud and said connecting part comprise means enabling to immobilize the proximal stud in rotation when the connecting part is engaged on this proximal stud, wherein the means comprise at least one flat surface provided on the proximal stud and at least one flat

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surface provided on the connecting part, whereas these flats surfaces are immediately close to one another when the connecting part is engaged on the proximal stud (see Fig above and Fig 10 and see Col 7 lines 8-20, where flat portions on the proximal stud and connecting part immobilize rotational movement).

Regarding **Claim 10**, it should be noted that the applicant is claiming an article of manufacture and not the process of forming/making the device, accordingly, the manner in which the device is formed (i.e. as recited above) is given little weight.

Taylor et al discloses a method for manufacturing the polyaxial anchoring member according to claim 1, comprising, on the part intended for the proximal stud of said polyaxial anchoring member, an articulation head in the form of a spherical cap; providing a cavity in the proximal zone of the part intended for said body of said anchoring member polyaxial, and, around this cavity, a wall which may be crimped; engaging said articulation head into said cavity, and crimping said wall around said articulation head so that this wall exhibits a proximal form at least partially hemispherical (see rejection in Claim 1 and Figs above as well as Col 5 lines 1-7).

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (See MPEP 21102.02)

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 3, 12, 14, 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765 in view of Stone et al US 5,443,482.

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Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used for gripping, where the collar cooperates with a tool #6). Taylor et al also discloses:

in Claim 12, at least one connecting part exhibiting a rounded section intended for surrounding a linking rod and two parallel drilled wings, the wings intended for engaging onto said proximal stud and for being clamped, the clamping means is capable to bear against a surface contained in said polyaxial anchoring member; the distal wing of the connecting part exhibits a distal cavity (#10 see Fig 2) in the form of a spherical cap, which is of greater diameter than that the crimped wall, the connecting part being intended for resting against this crimped wall (#57 as seen in Fig 10) at of this cavity (see Figs above as well);

in Claim 14, the stud exhibits a zone of reduced diameter, enabling to break its proximal portion after placing and clamping the nut (see Figs above and see Col 5 lines 31-42);

in Claim 17, the proximal stud and said connecting part comprise means enabling to immobilize the proximal stud in rotation when the connecting part is engaged on this proximal stud (see Fig above and Fig 10 and see Col 7 lines 8-20, where flat portions on the proximal stud and connecting part immobilize rotational movement).

Taylor et al does not specifically disclose four notches at 90 degrees to one another.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have four notches at 90 degrees to one another since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Furthermore, Stone et al discloses multiple tools with a socket having four corresponding notches at 90 degrees to match with corresponding four notches of an anchor (as seen in Figs 4, 5, 7-7a).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the collar of Taylor et al to have four notches at 90 degrees to each other as taught by Stone et al so that the collar of Taylor et al can cooperate with a tool having a corresponding female cavity to the notches, wherein the notches are a simple substitution of one known element for another to obtain predictable results for a tool/driver to grip a bone anchor/fastener/screw (see Figs 4, 5, 7-7a and abstract and see Col 2 lines 16-25).

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733